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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,577	12/16/2005	Tetsuro Kikuchi	Q86357	6428

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EXAMINER	
RAO, SAVITHA M	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,577	KIKUCHI ET AL.	
	Examiner	Art Unit	
	SAVITHA RAO	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 37-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 37-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/14/2008, 05/16/2008 and 08/15/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 37-69 are pending

Receipt of Applicants' amended claim set and remarks/arguments mailed on June 4th 2008 is acknowledged. Claims 1 is amended, Claims 2-36 are cancelled and claims 37-69 are new.

Applicants' arguments, filed 06/04/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed on 03/14/2008 05/16/2008 and 08/15/2008. The Examiner has considered the reference cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

. The "Japanese office action" on 1449 dated 06/24/2006 has been lined out because it is not a published document and therefore cannot have a date of publication which is required for a citation in the non-patent document area of 1449.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement Rejection (New grounds of rejection)

Claims 42, 44, 50,52, 54-59, 61 and 63-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating depression and major depressive disorder, does not reasonably provide enablement for treating other mood disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands,* 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims".

The nature of the invention

the present invention of claims 42, 44, 50 and 52 is drawn to a pharmaceutical

composition and methods comprising aripiprazole or its metabolite in combination with at least one serotonin reuptake inhibitors, in the preparation of a medicament for treating mood disorders. While claims, 54-59, 61 and 63-68 are drawn to a method of treating disorders in a patient comprising administration of an effective amount of a pharmaceutical composition comprising at least one aripiprazole or its metabolite in combination with at least one serotonin reuptake inhibitor.

The breadth of the claims

Instant claims encompass a pharmaceutical composition for treating mood disorders. It is noted that any disease may represent a "mood disorder". Therefore Applicants are claiming that the composition can treat any and all mood disorders and any and all symptoms associated with the mood disorders.

Quantity of Experimentation

The quantity of experimentation in this area is large since there is no reasonable expectation of success as the methods are not fully outlined in the specification. The specification only discloses working examples of treatments for depression and major depressive disorder. It is unclear in the specification how the plurality of diseases claimed can be treated by the claimed invention. The specification fails to address this issue.

Working Examples

The specification has several examples, however, aripiprazole with citalopram is the only tested combination and the tests and assays conducted are indicative for treatment of depression only.

The unpredictability of the art and the state of the prior art

It is generally recognized in the art that biological compounds often react unpredictably under different circumstances (Nationwide Chem. Corp. v. Wright, 458 F. supp. 828, 839, 192 USPQ 95, 105(M.D. Fla. 1976); Affd 584 F.2d 714, 200 USPQ 257 (5th Cir. 1978); In re Fischer, 427 F.2d 833,839, 166 USPQ 10, 24(CCPA 1970)). The relative skill of the artisan or the unpredictability of the pharmaceutical art is very high. Where the physiological activity of a chemical or biological compound is considered to be an unpredictable art (Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved" (See In re Fischer, 427 F.2d 833, 839, 166 USPQ 10, 24(CCPA 1970)), the skilled artisan would have not known how to extrapolate the results provided in the instant specification to the larger and varied genus of treatment of all disorders that currently exist or may exist in the future.

Guidance in the Specification

The examiner acknowledges that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP 2164.02). However, given the highly unpredictable state of the art and furthermore, given that the applicant does not provide sufficient guidance or direction as to how to make and use

the full scope of the instant claimed invention without undue amount of experimentation, the Office would require appropriate disclosure, in the way of scientifically sound reasoning or the way of concrete examples, as to why the data shown is a reasonably representative and objective showing such that it was commensurate in scope with and, thus, adequately enables, the use of aripiprazole in combination with any citalopram and milnacipran for the full scope of the presently claimed subject matter. Specification does not provide a direction for treatment In the absence of such guidance and evidence or reasoning, the specification fails to provide an enabling disclosure.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, the specification fails to provide written description or guidance that leads one to a readily ascertain which disorders are treatable by the combination of aripiprazole and the serotonin reuptake inhibitor citalopram or escitalopram. Thus given the an art whose nature is identified as unpredictable, the lack of guidance in the specification, the large quantity of research required to determine the correct methodology to employ, the presence of limited examples utilizing a working protocol, it is concluded that it would require undue experimentation for one of skill in the art to perform the method of the claims as written.

Response to applicant's argument

Applicant's remarks have been fully considered in their entirety, but fail to be persuasive.

In Particular Applicant states that "The present claims recite the term "mood disorders", which is specifically defined in medical text books and lists of medical disorders, such as the "Diagnostic and Statistical Manual of Mental Disorders" (DSM-IV) of the American Psychiatric Association or the International Classification of Diseases (ICD-10) of World Health Organization (WHO). "Mood disorders" mean that some disabilities occur in life such as persistence of depressive mood or persistence of abnormal mood elevation. The criteria were set from the standpoint that disorders should be diagnosed by symptoms and not consider causes of the disorders. For example, depression does not always develop by only one of the causes of the disorder. Accordingly, the classification was formulated based on a concept such that "it is reasonable to classify mental diseases according to their symptoms." Thus, "mood disorders" does not mean disorders (e.g., the disorders claimed in the present application per se) themselves, but defines the symptoms that appear in many disorders."

Applicant also refers to the original specification on pages 69 to 71 which discloses a tail suspension test, which is a kind of an antidepressant animal model test and states that "such an animal model shows symptoms defined by mood disorders. It is understood that a synergetic effect was exerted when citalopram and aripiprazole are used in combination in the test. Therefore, the term "mood disorders" in the claims is sufficiently supported by examples".

Examiner acknowledges the references supplied by the Applicant and the fact that "mood disorders"defines the symptoms that appear in many disorders is acknowledged. Examiner however would like to respectfully point out that the symptoms associated with these mood disorders are not limited by depression, other symptoms such as elevation of mood, urinary incontinence, gastrointestinal disorders, and cardiovascular effects among several others can be observed in certain "mood disorders". In the instant application treatment of "mood disorders" as claimed encompasses all types of symptoms associated with "mood disorders". The animal model test of the tail suspension test is specific to depression and accordingly does not encompass other conditions such as mood elevation, gastrointestinal effects etc. Accordingly, the new claim 42-44, 50-52 and 54-66 which recites the term "mood disorder" has been appropriately rejected under 112 1st scope of enablement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and new claims 37, 38, 40, 41, 43-45, 54-55, 58 and 60-62 are rejected under 35 U.S.C. 102(b), as being anticipated by WONG et al. (US 2002/0156067 A1, 24 October 2002) already of record, for the reasons of record set forth at page 8 of the previous office action dated 03/04/2008.

Instant claims 43-45 and 50-55 are drawn towards a composition and the intended use limitation recited in these claims has been give less patentability weight.

Newly added claims 37, 38, 41, 43-45, 54-55, 60-62 are properly included in this rejection because Wong expressly teaches pharmaceutical composition and methods of their use comprising a) one or more norepinephrine reuptake inhibitors and b) one or more neuroleptic agents (WONG claim 1). Among the compounds listed for component a) are duloxetine, venlafaxine, and milnacipran (WONG claim 2). These are the identical compounds listed as examples of serotonin reuptake inhibitors useful in the instant application (instant app claims 1, 37, 54 and 55). Among the compounds listed by WONG et al. as neuroleptic agents, component b), is aripiprazole (WONG claim 5). This is the exact compound presented in the instant application (instant app claims 1 and 54). Example 2 (WONG et al.) describes the preparation of the composition, in that the active components are combined in a pharmaceutically acceptable carrier (WONG page 6, column 1, paragraph 47, lines 1-3). Thus anticipating instant application claims 41 and 59. Wong discloses that the composition of his invention is used to treat any of the diseases or disorders of the central nervous system. Representative diseases or disorders include, but are not limited to the following: depression, schizophrenia, neurodegenerative disorders, migraine headaches, cluster headaches, an age-associated learning and mental disorder, bipolar disorder, a movement disorder (e.g., Tourette's syndrome)etc. ([0042] and claims 1,2,5,9 and 19 which are conditions overlapping those specifically recited in instant claims 42-45 and 54-55, 60-62.

With reference to aripiprazole crystals B claimed in instant claim 40 and 58, the compound and its characteristics cannot be separated, and the only difference between the aripiprazole taught by Wong and the aripiprazole crystals B is the physical form of the drug. Also Wong, is silent to the exact form of aripiprazole used. In the absence of evidence to the contrary the crystal form of aripiprazole must have the same characteristics and thereby elicit the same action as that used in Wong's reference Office lacks laboratory facilities to test the prior art compositions. It is incumbent upon applicants to provide data demonstrating that the properties of the disclosed prior art compositions are different from the claimed compositions.

Response to applicants' arguments:

Applicant's remarks have been fully considered in their entirety, but fail to be persuasive.

In particular, Applicant states that " Wong et al does not identically disclose the presently claimed invention as required for anticipation under 35 U.S.C. § 102. Specifically, Wong et al does not disclose an embodiment which includes all elements of the present claims. That is, Wong et al does not disclose specific combinations of aripiprazole and a norepinephrine reuptake inhibitor and neuroleptic agents. In order to arrive at the presently claimed invention, one would have to pick and choose among the listed compounds which are described as norepinephrine reuptake inhibitors and also among the listed neuroleptic agents. Such picking and choosing is not permissible in an anticipation rejection. Additionally, the number of potential

combinations of the disclosed norepinephrine reuptake inhibitors and neuroleptic agents is in the hundreds, perhaps thousands, and Wong et al does not express a clear preference for any of the compounds in the lists of norepinephrine reuptake inhibitors and neuroleptic agents of the reference that would meet the requirements of the present claims. .Accordingly, Wong et al does not describe an embodiment with sufficient specificity to anticipate the claims of the present invention within the meaning of 35 U.S.C. § 102" and " Wong et al does not disclose an identical composition, it cannot be said that it inherently has the same properties and could be used for the method of treating mood disorders as recited in the present claims"

First, it is noted that aripiprazole and the norepinephrine reuptake inhibitors venlafaxine, and milnacipran , as defined by Wong, is an umbrella term that includes the several other neuroleptics and norepinephrine reuptake inhibitors. Regardless, however, the fact that "aripiprazole" and "Venlafaxine and milnacipran" per se is inclusive of a number of other drugs used to treat similar conditions does not negate the fact that Wong expressly and unequivocally identifies aripiprazole as one of the neuroleptics and venlafexine and milnacipran as the norepinephrine reuptake inhibitors.. Applicant is reminded that a reference that clearly names the claimed species anticipates the claim no matter how many other species are named. Please reference MPEP §2131.02, which states, "A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Exparte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a

reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that 'the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds as described" as that term is used in 35 U.S.C. §102(a), in that publication'). Id. at 1718. See also In re Sivaramakrishnan, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982)." Wong et.al accordingly expressly discloses the combination as instantly claimed and specifically refers to the use of such combinations in the treatment of disorders of the central nervous system which includes several conditions of mood disorders as instantly claimed.

In response to applicant's argument, "Wong et. al does not disclose that the combination of aripiprazole with SRI exerts excellent treating or improving effects". One cannot separate the characteristics of the compound from the compound itself and since the combination of aripiprazole and the SRI as claimed in the instant application is expressly taught by Wong, the combination would exhibit the same properties as claimed in the instant claims. Office lacks laboratory facilities to test the prior art compositions. It is incumbent upon applicants to provide data demonstrating that the properties of the disclosed prior art compositions are different from the claimed compositions

For these reasons, and those previously made of record at page 8-9 of the previous Office Action dated March 4th 2008, rejection of claims 1 and new claims 37,

38, 41, 43-45, 54-55 and 60-62 remains proper and is maintained.

Claim Rejections - 35 USC § 103

(New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 38-39, 46-53, 56-57 and 63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al(US 2002/0156067, already of record) in view of Winnans (American Journal of Health-system and pharmacy, vol. 60, Dec 1, 2003; page 2437-2447)

Wong expressly teaches pharmaceutical composition and methods of their use comprising a) one or more norepinephrine reuptake inhibitors and b) one or more neuroleptic agents (WONG claim 1). Among the compounds listed for component a) are duloxetine, venlafaxine, and milnacipran (WONG claim 2). These are the identical compounds listed as examples of serotonin reuptake inhibitors useful in the instant application (instant app claims 1, 37, 54 and 55). Among the compounds listed by WONG et al. as neuroleptic agents, component b), is aripiprazole (WONG claim 5). This is the exact compound presented in the instant application (instant app claims 1 and 54). Example 2 (WONG et al.) describes the preparation of the composition, in that the active components are combined in a pharmaceutically acceptable carrier (WONG page 6, column 1, paragraph 47, lines 1-3). Thus anticipating instant application claims 41 and 59. Wong discloses that the composition of his invention is used to treat any of the diseases or disorders of the central nervous system. Representative diseases or disorders include, but are not limited to the following: depression, schizophrenia, neurodegenerative disorders, migraine headaches, cluster headaches, an age-associated learning and mental disorder, bipolar disorder, a movement disorder (e.g., Tourette's syndrome)etc. ([0042] and claims 1,2,5,9 and 19 which are conditions

overlapping those specifically recited in instant claims 42-45 and 54-55, 60-62. Wong teaches that both commonly used typical and atypical neuroleptic agents can cause number of neurological side effects [0013-0014]. Wong also teaches the need for a pharmaceutical compositions that would have both the therapeutic benefits of the neuroleptics agents (typical or atypical) but with reduced side effects [0013]. Furthermore Wong teaches that the combination of the norepinephrine reuptake inhibitor with a neuroleptic provides rapid relief to those suffering from disorders of the central nervous system with a minimal amount of deleterious side effects [0044].

Wong does not specifically teach metabolites of aripiprazole such as dehydroaripiprazole etc. or wherein aripiprazole is anhydrous aripiprazole crystals B or the norepinephrine reuptake inhibitor to be specifically escitalopram or citalopram.

Winans teaches the pharmacology, pharmacokinetics, clinical efficacy, adverse effects, drug interactions and dosage of aripiprazole (abstract). Winans teaches that the major metabolite of aripiprazole is dehydro-aripiprazole which has demonstrated similar affinities for D2 receptors and represents approximately 40% of aripiprazole's AUC in the plasma (page 3, left col. 3rd paragraph). Additionally, Winann teaches that when aripiprazole was administered with divalproex moderate change in pharmacokinetic parameters were observed and similar effects were observed when the active metabolite was administered with divalproex (page 7, right col., and 3rd paragraph). As such, the substitution of aripiprazole taught by Wong with its metabolites such as dehydro-aripiprazole would have been *prima facia* obvious to one of ordinary skill in the

art because the metabolites are expressly taught in the prior art to have similar activity as the parent drug.

With references to the specific serotonin reuptake inhibitors citalopram and escitalopram claimed in the instant application, these two drugs elicit anti-depressant effect by inhibiting serotonin reuptake. Although Wong is silent as to these specific drugs, Wong cites drugs such as venlafaxine, which also inhibits serotonin reuptake as evidenced by applicants as evidenced by Harvey et al (Arch Gen Psychiatry/ vol 57, May 2000, page 503-509). Harvey teaches that venlafaxine is an antidepressant with a mechanism of action that is believed to involve inhibition of the uptake pumps for serotonin and norepinephrine (page 503, left col. 1st paragraph) and concludes that the in-vivo evidence in healthy humans suggests that both serotonin (5-HT) and norepinephrine uptake inhibitions are mechanisms of action of venlafaxine. Citalopram and escitalopram are also serotonin reuptake inhibitors as evidenced by Owens (CNS Spectr, abstract, 2002 Apr/ 7 (4) page 34-9). Owens teaches that citalopram is one of a selective serotonin reuptake inhibitor and it's S-enantiomer also known as escitalopram is one of the most selective serotonin reuptake inhibitor available. As such venlafaxine taught by Wong is a functional equivalent of citalopram and escitalopram and thus substitution of the antidepressants taught by Wong with other similarly functioning drugs such as citalopram or escitalopram would have been obvious to one of ordinary skill in the art at the time of invention.

In view of the foregoing references, the instantly claimed pharmaceutical composition would have been prima facia obvious to one of ordinary skill in the art at

the time the invention was made. Wong teaches pharmaceutical composition comprising of (a) one or more norepinephrine reuptake inhibitors and (b) one or more neuroleptic agents. Accordingly all of the materials instantly claimed were known in the art to be for treatment of the disorders of the central nervous system. The prior art also teaches solution to the problem of decreasing adverse effects experienced with treatment of neuroleptics alone. This solutions to the prior art problem which is the combination of the neuroleptics with norepinephrine reuptake inhibitors also provides the skilled artisan motivation to combine the references. An ordinarily skilled artisan will be imbued with at least a reasonable expectation of success that a compositions comprising the serotonin, norepinephrine receptor uptake inhibitors with known neuroleptics will result in the decrease of deleterious effects associated with neuroleptic treatment alone.

Conclusion

Claims 1, 37-69 are rejected. No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7.00 am to 4.00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/

Examiner, Art Unit 1614

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614